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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,448	05/22/2006	Kazutomo Inoue	2005_0611A	6960

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,448	INOUE ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 20-32* is/are pending in the application.

4a) Of the above claim(s) *1-4,6-9 and 20-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/28/2008, 4/14/2005, 11/3/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A response and amendment were received and entered on November 10, 2008. All evidence and arguments have been fully considered. New claims 31 and 32 have been added. Claims 1-9 and 20-32are pending. Claims 1-4, 6-9 and 20-29 are withdrawn from further consideration due to a prior requirement for restriction. Claims 5 and 30-32 are examined on the merits in this office action.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on April 14, 2005, March 28, 2008 and November 3, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Declaration under 37 CFR 1.132

3. The declaration under 37 CFR 1.132 filed November 10, 2008 is insufficient to overcome the rejections set forth in this Office action because:

4. It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. Specifically, applicant's evidence is directed only to methods wherein a reconstituted freeze-dried fibrin is administered to wounds in mice. There is no evidence to demonstrate that there is any advantage to the administration of a non-reconstituted

fibrin or an injected fibrin, as recited in the claims, or to the administration of the concentrations of the freeze-dried fibrin recited in the claims.

5. Furthermore, applicant argues that the claimed invention provides superior results to prior art methods of administering fibrin. However, the evidence provided in applicant's declaration demonstrates only that methods involving the administration of fibrin are advantageous over methods wherein no fibrin is administered. This advantage was known in the prior art at the time of the invention, as discussed below.

6. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claim Rejections - 35 USC § 112

7. Rejections under 35 USC 112 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 101

8. Rejections under 35 USC 101 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 5 and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwardson et al. (US 5,739,288). The claims recite a method of inducing angiogenesis comprising treating a living body with a granule preparation containing freeze-dried fibrin, wherein the granule preparation is administered by injection or external application. The claims further recite that the method further comprises preparing an aqueous suspension preparation for injection by suspending the granule preparation containing freeze-dried fibrin in a liquid excipient before treating, wherein the compounding ratio of the excipient and the granule preparation is 100 to 500 microliters of the excipient per 4 mg of the granule (note that 4 mg per 0.1 to 0.5 microliters equals 8 to 40 mg per milliliter).

11. Edwardson teaches a granule preparation comprising a lyophilized (i.e., freeze-dried) fibrin (col. 17, lines 30-36) and a method of treating a living body with the preparation by external application (col. 18, lines 5-14). Edwardson also teaches that the composition may be suspended in a liquid excipient at 25 to 50 mg per milliliter (col. 5, lines 33-42). The fibrin of Edwardson would promotes wound-healing (col. 18, lines 15-42), and thus would inherently induce angiogenesis.

12. Therefore, the reference anticipates all of the limitations of the claims.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 5 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwardson et al. (US 5,739,288). The claims recite a method of inducing angiogenesis comprising treating a living body with a granule preparation containing freeze-dried fibrin, wherein the granule preparation is administered by injection or external application. The claims further recite that the granule preparation is administered to a living body at 1 to 10 mg per square centimeter of a surface area of a living body and that the method further comprises preparing an aqueous suspension

preparation for injection by suspending the granule preparation containing freeze-dried fibrin in a liquid excipient before treating, wherein the compounding ratio of the excipient and the granule preparation is 100 to 500 microliters of the excipient per 4 mg of the granule (note that 4 mg per 0.1 to 0.5 microliters equals 8 to 40 mg per milliliter).

17. Edwardson teaches a granule preparation comprising a lyophilized (i.e., freeze-dried) fibrin (col. 17, lines 30-36) and a method of treating a living body with the preparation by external application (col. 18, lines 5-14). Edwardson also teaches that the composition may be suspended in a liquid excipient at 25 to 50 mg per milliliter (col. 5, lines 33-42). The fibrin of Edwardson would promotes wound-healing (col. 18, lines 15-42), and thus would inherently induce angiogenesis.

18. Edwardson does not specifically teach that the granule preparation is administered to a living body at 1 to 10 mg per square centimeter of a surface area of a living body, however the reference does discuss that the preparation may contain from 10 to 200 mg per milliliter in solution (col. 5, lines 33-42) and that 0.05 to 40, specifically 3 to 5, milliliters of the preparation may be administered to wounds (col. 18, lines 15-57). Based upon the ranges provided in Edwardson, one of ordinary skill in the art would have been motivated to apply the claimed amount to a wound (e.g. 3 milliliters of a solution containing 10 mg per milliliter of the preparation to an average wound of 4 square centimeters would result in the administration of 7.5 mg of the preparation per square centimeter) or could have arrived at the claimed amount in the course of routine experimentation. One would have had a reasonable experimentation of success in using the claimed amount because Edwardson teaches that the administration of the

preparation in such amounts is suitable for treatment. It would therefore have been obvious to modify the teachings of Edwardson to arrive at the claimed invention.

19. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

20. Applicant's arguments with respect to the rejections of the previous office action have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/ Primary Examiner, Art Unit 1651